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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,339	09/10/2002	Paul Sherwood	13596-003US1	2886

7590

08/01/2003

Fish & Richardson
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EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,339

Applicant(s)

SHERWOOD ET AL.

Examiner

Clinton Ostrup

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 10-24 are pending in this application.

Priority

Priority to PCT/GB00/03490 filed September 12, 2000 and United Kingdom Application Number 9921985.9, filed September 16, 1999, has been acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 10-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 also recites the limitation "said inflammation or pain," however, there is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the spinal vertebrae," however, there is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the calcium salt," however, there is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the injectable medicament," however, there is insufficient antecedent basis for this limitation in the claim.

Claims 20-22 recite the limitation "the medicament," however, there is insufficient antecedent basis for this limitation in the claims.

Any remaining claims are rejected as depending on indefinite base claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hyodo et al., 5,260,289.

Hyodo et al teach a method of using a composition comprising NEO VITICAN™, which comprises 100 mg/100 ml of calcium pantothenate and 100 mg/100ml of dibucaine hydrochloride (a local anesthetic), for the local treatment of pain; thus, meeting the specific limitations of instant claims 10-13, 15 and 20. See: col. 1, lines 11-50 and abstract. The reference teaches that the composition is useful for the treatment of chronic rheumatism, low backache, backache, frozen shoulder, thus meeting the disorder limitations of instant claim 11 and that the composition is injected locally into mammals. See: col. 2, lines 35-51; col. 3, line 19 – col. 4, line 7; col. 5, line 12 – col. 6, line 68. Finally, the reference teaches that the compositions are prepared into injections when in use and gives an aqueous solution as an example of how the compositions may be prepared. See: col. 3, lines 46-66. Therefore, Hyodo et al clearly anticipate the instantly claimed limitations of claims 10-15 and 20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-16 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al., as applied to claims 10-15 and 20 above, and further in view of UK Patent Number 1,145,623 (623).

Hyodo et al teach a method of using a composition comprising NEO VITICANTM, which comprises 100-mg/100 ml of calcium pantothenate and 100 mg/100ml of dibucaine hydrochloride (a local anesthetic), for the local treatment of pain. See: col. 1, lines 11-50 and abstract. The reference teaches that the composition is useful for the treatment of chronic rheumatism, low backache, backache, frozen shoulder, thus meeting the disorder limitations of instant claim 11 and that the composition is injected locally into mammals. See: col. 2, lines 35-51; col. 3, line 19 – col. 4, line 7; col. 5, line 12 – col. 6, line 68. Hyodo et al teach that the compositions are prepared into injections when in use and gives an aqueous solution as an example of how the compositions may be prepared. See: col. 3, lines 46-66.

However, the primary reference lacks the cysteine or glucosamine of instant claim 16 and 21.

623 teaches compositions useful in the treatment of osteoarthritis and rheumatoid arthritis. The secondary reference teaches a composition comprising d-pantothenic acid and cysteine for parenteral administration. The 623 reference also teaches that although it has previously reported to use calcium d-pantothenate for the alleviation of arthritis, greatly improved results are obtained in the treatment of osteoarthritis, when pantothenate and cysteine are administered together.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of pain treatment as taught by Hyodo et al, by using pantothenic acid in combination with cysteine, as taught by 623 because of the reasonable expectation of obtaining a method of locally treating rheumatic pain with a combination of medicaments which have greatly improved results when administered together.

Claims 10-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al taken with UK Patent Number 1,145,623 (623), as applied to claims 10-16 and 20-21 and further in view of Rozenberg, RU 2078564C1.

Rozenberg teaches compositions comprising dipalmitoyl phosphatidylcholine for the treatment of septic inflammations and that they can be treated more effectively by administering glucocorticoids whose anti-inflammatory effects have been enhanced by incorporating them in a liposome membrane dipalmitoyl phosphatidylcholine. The reference teaches the compositions as being useful for treating inflammatory diseases such as rheumatoid arthritis and that acute inflammation symptoms are alleviated after

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a single injection without side-effects by using only 1/3 of the dosage associated with finely-crystalline hydrocortisone forms. See: abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating pain as taught by the combined references above by adding phospholipids such as dipalmitoyl phosphatidylcholine as taught by Rozenberg because of the reasonable expectation of obtaining a method of treating pain and inflammation by with a liposomal membrane that would allow injection of the composition without side effects, using a lesser amount of active ingredients.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Clinton Ostrup
Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Clinton Ostrup', with a long horizontal flourish extending to the right.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Frederick Krass', with a long horizontal flourish extending to the right.

July 26, 2003